



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,406	03/29/2006	Bernadette Verneau	065691-0397	3436

22428 7590 08/14/2008
FOLEY AND LARDNER LLP
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER

MI, QIUWEN

ART UNIT	PAPER NUMBER
----------	--------------

1655

MAIL DATE	DELIVERY MODE
-----------	---------------

08/14/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/542,406	Applicant(s) VERNEAU, BERNADETTE	
	Examiner QIUWEN MI	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 14-23 and 25-34 is/are pending in the application.
- 4a) Of the above claim(s) 15, 16, 23 and 26-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 14, 17-22, 25, 33 and 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendment in the reply filed on 7/2/08 is acknowledged. Any rejection that is not reiterated is hereby withdrawn. Claims 2-13, and 24 are cancelled. Claims 1, and 14-23, and 25-34 are pending. Claims 15, 16, 23, and 26-32 are withdrawn as they are directed toward a non-elected invention groups or species. **Claims 1, 14, 17-22, 25, 33, and 34 are examined on the merits.**

Claim Rejections –35 USC § 112, 1st New Matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 14, 17-22, 25, 33, and 34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

Claim 1 adds the new limitation “wherein the composition is solid or pasty at room temperature”. However, the specification fails to provide any support regarding the description of “wherein the composition is solid or pasty at room temperature”. The specification only support a lipophilic additive which is solid or pasty at room temperature, which is very different from the whole composition is solid or pasty at room temperature. Therefore, it is not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, Applicant had possession of the “wherein the composition is solid or pasty at room temperature”

Art Unit: 1655

in the invention. Thus, the subject matter of “wherein the composition is solid or pasty at room temperature” is a new matter that needs to be cancelled.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, first paragraph for the reasons set forth above.

Claim Rejections –35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 14, 17, 19, 33, and 34 are rejected under 35 USC § 102 (b) as being anticipated by Buckholz, Jr et al (US 4,999,207).

This is a new rejection.

Buckholz, Jr et al teach ground sausage comprising Ground beef 200.0, Beef suet 120.0 (thus a solid lipophilic additive at 6.8% (120/1770, inherently contains fatty acids), Ice/NaCl (50:50 mixture) 200.0, Potato flour 100.0, Anhydrous bread crumbs 140.0, Dry milk powder 20.0, Standard spice flavor 10.0, containing: Oil of cumin 1.6, Oil of mustard 3.3, Oil of celery 3.3, Oil of ginger (physiologically active component) 5.2, Oil of cloves (physiologically active component) 14.3, Oil of coriander 17.6, Oil of pimenta berries 22.0, Oil of black pepper 43.0,

Art Unit: 1655

Oleoresin capsicum (inherently contains capsaicinoids) 373.0, Oil of nutmeg (thus nut oil) 500.0.

The intended use of the composition was analyzed for patentable weight. It is deemed that the preamble 'breathes life' into the claims in that the prior art product must not be precluded for use to stimulate thermogenesis. It is deemed that the composition disclosed by the cited reference is not precluded for carrying out the intended function of the claims.

Therefore, the reference is deemed to anticipate the instant claim above.

Claim Rejections –35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 14, 17-22, 25, 33, and 34 remain rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Mann (US 5,273,754), Mamana (US 2002/0192308), and Hosoya et al (JP 2001064672 A).

This rejection is maintained for reasons of record set forth in the Office Action mailed out on 4/2/2008, repeated below, slightly altered to take into consideration Applicant's amendment filed on 7/2/08. Applicants' arguments filed have been fully considered but they are not deemed to be persuasive.

Mann teaches an appetite suppressant composition leading to a decrease in weight (col 1, lines 5-10) comprising a heating carminative substance, such as standard oleoresin capsicum which contains capsaicin (thus capsaicinoids) (thus in the form of capsicum resin) (col 2, lines 45-50), and a cooling carminative substance selected from peppermint, menthol, and spearmint etc (thus contains a vegetable oil) (claim 3; example 2). Mann also teaches that capsaicin is a preferred heating carminative substance, ...having a gastric heating effect exhibits a local anesthetic effect in the stomach (particularly upon the gastric nerves controlling hunger) when administered orally at a sufficient dose (col 2, lines 30-40). Mann further teaches that the appetite suppressant composition in a form suitable for oral administration, and preferably as a capsule (thus solid or pasty at room temperature) (col 4, lines 22-28).

Mann does not teach the incorporation of soya oil, and green tea into the composition, and neither does Mann teaches the claimed amount of the components.

Mamana teaches an appetite suppressant for controlling weight comprising green tea or green tea leaf extract (thus one or more physiologically active components) (claim 1). Mamana also teaches a method of controlling weight by replacing at least one meal with a soy based meal replacement (claim 22) (thus contains soya oil, a vegetable oil). Mamana further teaches that the appetite suppressant is preferably administered orally in the form of a capsule etc (thus solid or pasty at room temperature) [0014].

Art Unit: 1655

Hosoya et al teach a fat metabolizer ingested (thus acceptable for oral administration) in very small amount comprising fats and oils consisting of diglyceride and/or monoglyceride, triglyceride (thus a lipophilic additive, solid or pasty at room temperature), linseed oil (thus a vegetable oil) etc. Hosoya et al also teach that the obtained fats and oils filled in a soft capsule (thus solid or pasty at room temperature). Hosoya et al teach that the results obtained showed that BMI, body fat rate and waist size were efficiently reduced without changing the eating habits of the persons (see Abstract, full translation has been ordered).

"It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose ...[T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted).

In the instant case, all of the above-listed ingredients were known for weight control. Thus, one of ordinary skill in the art would have had a reasonable expectation that the combination of these compounds would have been additively beneficial in weight control.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for weight control. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the

Art Unit: 1655

results obtained thereby are no more than the additive effect of the ingredients, In re Sussman, 1943 C.D. 518.

It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 220 F.2d 454, 456, 105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. Although the prior art did not specifically disclose the amounts of each constituent as in the claims, it would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of components because concentration is an art-recognized result-effective variable which would have been routinely determined and optimized in the pharmaceutical art.

Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him.

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to combine the inventions of Mann, Mamana, and Hosoya et al since all of them teach compositions for weight control individually in the art. Since all the compositions yielded beneficial results in weight control, one of ordinary skill in the art would have been motivated to make the modifications. Regarding the limitation to the amount of the components in the composition, the result-effective adjustment in conventional working parameters is deemed merely a matter of judicious selection and routine optimization which is

Art Unit: 1655

well within the purview of the skilled artisan, which is dependent on the body weight, age, and appetite of the patient that is needed.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Applicant argues that “Mann et al. does not teach to add any formulation base containing a vegetable oil and/or mineral oil and a lipophilic additive which is solid or pasty at room temperature as in the invention, since it only discloses adding either "cooling carminative substances" (e.g. peppermint, menthol, spearmint, carvone or mixture thereof), amino acid (e.g. L-methionine, D-phenylalanine, glycine and mixtures thereof), and/or anxiolytic substance (e.g. valerian, damiana, chamomile, kava, passion flower, hops, skullcap, St John's Wort, extracts thereof or mixtures thereof). Furthermore, neither Mamana et al., nor Hosoya et al., which disclose respectively an appetite suppressant composition and a weight reducing composition, teach to counteract the gastric burning effect of the capsaicinoids by the use of formulation base containing a vegetable oil and/or mineral oil and a lipophilic additive. Finally, none of these documents teach the use of lipophilic additive which is solid or pasty at room temperature in their composition” (page 8, last paragraph; page 9, 1st-3rd paragraph).

This is not found persuasive. Hosoya et al teach a fat metabolizer ingested (thus acceptable for oral administration) in very small amount comprising fats and oils consisting of diglyceride and/or monoglyceride, triglyceride, and triglyceride, for example, is a lipophilic additive that is

solid or pasty at room temperature. Therefore, the cited references teach the limitations of the present invention.

Applicant's arguments have been fully considered but they are not persuasive, and therefore the rejection in the record is maintained.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number: 10/542,406
Art Unit: 1655

Page 10

QM

/Michael V. Meller/

Primary Examiner, Art Unit 1655